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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BARNES & THORNBURG LLP 11 SOUTH MERIDAN STREET INDIANAPOLIS, IN 46204			EXAMINER BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/631,339

Applicant(s)

WITTWER ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-12,15,19,20,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-12,15,19,20,23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 24 is objected to because of the following informalities: Claim 24 depends from cancelled claim 21. It appears that claim 24 should depend from claim 23 and will be examined on its merits as though it depends from claim 23. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3, 5, 6, 9, 10, 11, 15, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985) in view of Fite et al.(US 5,142,143).

The reference of von Behrens discloses a container (12) for holding a fluidic biological sample that includes a receiving portion (12a) and a reaction portion (12b). A liquid sample positioned within the receiving portion (12a) is capable of flowing into reaction portion (12b). As shown in Figure 1, the receiving portion (12a) has a volume greater than the reaction portion (12b). The reaction volume is not greater than 100 μ l (See column 4, lines 26-35). With respect to the recited thermal conductivity of the reaction portion, the reference of von Behrens discloses that the reaction portion (12b) is made of glass (See column 4, line 33) which is a material disclosed by the instant specification as a material with the claimed thermal conductivity (See page 53 of the instant specification). The reference of von Behrens discloses that the end of the reaction portion (12b) can be permanently sealed (See column 5, lines 57-67, and Figure 6). With respect to the claimed “wherein the closed end is formed for optical transmissibility through the closed end”, the closed end of the reference of von Behrens as discussed previously is considered to meet this claim limitation since it is made of a transparent glass (See column 5, lines 57-67, Figure 6 and column 4, line 33).

With respect to claims 1, 23 and 24, while the reference of vonBehrens discloses that portion (12b) of the inner tube device is a **microhematocrit tube** and can vary in volumetric capacity between 0.5 and 100 cubic millimeters (See column 5, lines 24-36), the reference is

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silent with respect to the wall thickness of the tube. Instant claims 1, 23 and 24 specify a “thin wall” or “0.1mm” thickness.

The reference of Fite et al. discloses that **microhematocrit tubes** having a wall thickness of 0.1mm is known in the art (See column 11, lines 18-24).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the microhematocrit tube disclosed by the reference of Fite et al. as element (12b) of the reference of von Behrens for the known and expected result of providing an art recognized microhematocrit tube within the system of von Behrens as is required of the device of the primary reference.

The instant claim language employs the transitional language “consisting”. The device of von Behrens discloses the additional structure (11). However, this structure is only required when supporting the inner tube (12) within a centrifuge device.

As a result, it would have been obvious to one of ordinary skill in the art to provide the inner tube device (12) as a separate structure from the outer tube device for the known and expected result of using off the self-type of outer tubes (11) that would be provided separately from the inner tube device (12) prior to use. As a result, the inner tube structure (12) alone would meet the structure of instant claims 1, 23 and 24.

With respect to claim 2, the reference of von Behrens discloses that the upper section or receiver portion (12a) is made of plastic (See column 5, lines 40-46).

With respect to claim 3, the reference of von Behrens discloses that the upper section or receiver portion (12a) is funnel shaped (See Figure 1).

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With respect to claims 5, 9, 10 and 19, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to optimize the dimensions of the tube based merely on the desired volume of liquid to be drawn into the capillary vessel.

With respect to claim 6, the reaction portion (12b) is made of glass which is transparent.

With respect to claim 11, the specifics of the interface between the funnel-shaped upper portion (12a) and the lower portion (12b) would have been well within the purview of one having ordinary skill in the art while maintaining a fluid seal between the separate elements (See column 5, lines 33-47).

With respect to claim 15, the reaction portion has a v:sa ratio of less than 1mm or 0.25mm (See column 4, lines 26-35).

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985) in view of Fite et al.(US 5,142,143) taken further in view of Gerarde (US 3,518,804).

The combination of the references of von Behrens and Fite et al. has been discussed above.

Claim 4 differs by reciting that the receiver portion includes a plug.

The reference of Gerarde discloses that it is known in the art to seal the receiver portion (12) of the device that is similar in structure to the device of the modified primary reference with a plug (24) (See Figure 3).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide the receiving

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section (12a) of the modified primary reference with a plug for the known and expected result of sealing the open end of the tube during storage of the device to protect the interior from contamination and/or protect a contained sample from contamination, exposure and/or leakage from the container.

7. Claims 12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985) in view of Fite et al.(US 5,142,143) taken further in view of Hawes (US 3,556,659).

The combination of the references of von Behrens and Fite et al. has been discussed above.

While the reference of von Behrens discloses that the end of the tube may be sealed (See column 5, lines 63-65 and Figure 6), the reference does not disclose that the sealed end is flat or permits light having a wavelength of about 400nm to about 800nm.

The reference of Hawes discloses that it is conventional in the art to seal the end of a capillary tube such that it forms a flat tip (See Figures 2a and 3-5).

In view of this teaching, it would have been obvious to one having ordinary skill in the art at the time the invention was made to seal the end of the capillary using forming a flat tip as suggested by the reference of Hawes for the known and expected result of providing an alternative means recognized in the art to seal the end of a capillary tube. The method disclosed by the reference of Hawes provides a capillary tube that is capable of being optically interrogated through the end of the capillary tube. Additionally, since glass is employed, it would be capable of passing light in the range of 400nm to 800nm as required of the instant claims.

Response to Arguments

8. With respect to the rejection of Claim 21 under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985), this rejection has been withdrawn since claim 21 has been cancelled.

9. With respect to the rejection of Claims 1-3, 5, 6, 9, 10, 11, 15, 21 and 22 under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985) in view of Fite et al.(US 5,142,143), Applicants argue that the rejection is improper for the following reasons.

With respect to the “consisting of” language, Applicants argue (See pages 6-8 of the response filed 4/19/06) that the reference of von Behrens fails to support and/or provide motivation for the separation of the outer tube from the inner tube as speculated by the Examiner. Applicants stress that the simple fact that a portion of the device could be manufactured as a separate component cannot provide the sole basis of obviousness of the component as a separate entity. Applicants stress that the Examiner must provide some teaching or suggestion regarding the desirability of preparing the inner tube device. Finally Applicants point out that the outer tube does more than simply support the inner tube because the reference discloses an interflow of fluid between the tubes.

In response to Applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or **in the knowledge**

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generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, while the reference of von Behrens discloses the combination of the inner tube and outer tube during the centrifugation step, the reference also clearly discloses that the inner tube structure is intended to be removed from the outer tube structure (See column 2, lines 30-39) during the processing steps. Clearly one of ordinary skill in the art would recognize that the inner tube structure can be and is provided as a separate component and at some points during the processing steps is provided as a single component absent the outer tube. Furthermore, one of ordinary skill in the art would clearly recognize that by separately providing the inner tube from the outer tube, the outer tube can be reused.

With respect to the combination of the references of von Behrens and Fite et al., Applicants argue (See pages 8-11 of the response filed 4/19/06) that many capillary tubes that do not have the claimed wall thickness exist and the Examiner has merely cited one reference of a capillary tube that falls within the claim language but has not provided any motivation for selecting this tube over the other tubes. Applicants stress that in view of the disclosure of von Behrens, one of ordinary skill in the art would have been motivated to employ a tube with a thicker wall to prevent breaking of the tube. Applicants also point out that the wall thickness of the tube of the instant invention has been chosen for a specific reason, conducting rapid thermal cycling.

In response, the motivation for combining the references is provided in the references. First, the reference of von Behrens discloses that a microhematocrit tube is employed in the device (See column 7, lines 44-65). The reference also discloses that the dimensions of the tubes

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are not critical and can vary. As a result, one of ordinary skill in the art would have recognized and/or been motivated to employ any known microhematocrit tube, such as that disclosed by the reference of Fite et al. The fact that the tube of Fite et al. may be more fragile than other known tubes is immaterial, since the reference of von Behrens recognizes that the tubes are fragile. The reference is completely silent with respect to the use of tube with wall thicknesses greater than others to avoid breakage of the tube. Furthermore, one of ordinary skill in the art would also be motivated to employ the tube of Fite et al. over other tubes for the known and expected advantage of providing a tube that provides rapid heat exchange, especially when performing microhematocrit operations that require temperature control. Finally, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

10. With respect to the rejection of Claim 4 under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985) in view of Fite et al.(US 5,142,143) taken further in view of Gerarde (US 3,518,804), Applicants argue (See pages 11-12 of the response filed 4/19/06) that the reference of Gerarde fails to make up for the deficiencies previously argued with respect to the combination of the references of von Behrens and Fite et al.

In response, the reference of Gerarde was relied upon merely to address the additional claim limitations of claim 4 and not those of independent claims 1, 4 or 21. The Examiner maintains that the combination of the references of von Behrens and Fite et al. is proper for reasons already of record.

11. With respect to the rejection of Claims 12 and 20 under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985) in view of Fite et al.(US 5,142,143) taken further in view of Hawes (US 3,556,659), Applicants argue that the rejection is improper for the following reasons.

First, Applicants argue (See page 12 of the response filed 4/19/06) that there is no motivation to combine the reference of Hawes with the references of von Behrens and Fite et al. because Hawes is drawn to optical interrogation while the references of von Behrens and Fite et al. are silent with respect to optical interrogation.

In response, while the references of von Behrens and Fite et al. may be silent with respect to optical interrogation, the references require a sealed end. The reference of Hawes provides evidence that it is known in the art to seal the end of a capillary tube to have a flat surface. As a result, one of ordinary skill in the art would have recognized that the tube of the modified reference can be sealed with a flat end merely as an alternative means for sealing the end of a capillary tube recognized in the art. The flat surface allows the tube to be optically interrogated while reducing background light.

Finally Applicants argue (See pages 12-13 of the response filed 4/19/06) that the reference of Hawes does not disclose a tube with a flat tip. Applicants stress that the end of the tube of Hawes must be convexed.

In response, while the optical detection system of the reference of Hawes requires that the tube be interfaced with a convex lens, the reference still discloses that a capillary tube can be sealed with a flat tip wherein the flat tip is interfaced with the convex lens during the optical

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interrogation. Clearly one of ordinary skill in the art would recognize that the tube ends can be sealed separately from the lens as disclosed in the reference of Hawes. Additionally, one of ordinary skill in the art would have recognized that when sealing the end of the tube for processing as required of the modified primary reference, the additional convex lens would not be required.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB